

Notice of Allowability

Application No.

10/807,553

Applicant(s)

MOCHLY-ROSEN, DARIA

Examiner

Karen Cochrane Carlson, Ph.D.

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to November 21, 2005.
2. ☒ The allowed claim(s) is/are 27,29,31 and 34-64.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 3/04
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

Art Unit: 1653

This Notice of Allowability is in response to the election filed November 21, 2005 and to the acceptance of the Examiner's Amendments as set forth below. Claims 1-26, 28, 30, and 32 have been cancelled. Claims 27, 29, 31, and 33-54 are currently pending and under examination.

Priority is to November 10, 2000.

An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Judy Mohr on January 26, 2006.

Examiner's Amendments to the Claims:

Please amend the following claims:

27. (Currently Amended) A composition comprising a [ψ ϵ RACK] peptide having a sequence that [is] shares at least [about] 50% [identical] identity [to] with SEQ ID NO: 2, said peptide having the ability to selectively activate epsilon protein kinase C (ϵ PKC) function in cardiac myocytes, said peptide attached by an N-terminal cysteine residue to a Tat-derived peptide or to a polyarginine peptide.

29. (Currently Amended) The composition of claim 27, wherein said [ψ ϵ RACK] peptide [has] shares a sequence that is at least [about] 70% [identical to] identity with SEQ ID NO: 2.

31. (Currently Amended) The composition of claim 27, wherein said [ψ ϵ RACK] peptide [has] shares a sequence that is at least [about] 80% [identical to] identity with SEQ ID NO: 2.

34. (Currently Amended) A method for reducing *in vivo* damage due to ischemia, hypoxia, or reperfusion injury in a subject, comprising administering to said subject the peptide according to claim 27.

40. (Currently Amended) A method for reducing *in vivo* damage to an organ due to ischemia, hypoxia, or reperfusion injury in a subject, comprising administering to said subject the peptide according to claim 27.

Art Unit: 1653

47. (Currently Amended) A method for reducing *in vivo* cellular damage due to ischemia, hypoxia, or reperfusion injury in a subject, comprising administering to said subject the peptide according to claim 27.

55. (New) A method for reducing damage to an ex vivo organ due to ischemia, hypoxia, or reperfusion injury, comprising administering to said organ the peptide according to claim 27.

56. (New) The method of claim 55, wherein the method is for reducing damage to an organ selected from the group consisting of heart, lung, liver, brain, and kidney.

57. (New) The method of claim 55, wherein said administering comprises administering the peptide prior to ischemia, hypoxia, or reperfusion.

58. (New) The method of claim 55, wherein said administering comprises administering the peptide after ischemia, hypoxia, or reperfusion.

59. (New) The method of claim 55, wherein said administering comprises administering the peptide during ischemia, hypoxia, or reperfusion.

60. (New) A method for reducing damage to a cell due to ischemia, hypoxia, or reperfusion injury, comprising administering to said cell the peptide according to claim 27.

61. (New) The method of claim 60, wherein the method is for reducing damage to a cell selected from the group consisting of heart cells, lung cells, liver cells, brain cells, and kidney cells.

62. (New) The method of claim 60, wherein said administering comprises administering the peptide prior to ischemia, hypoxia, or reperfusion.

63. (New) The method of claim 60, wherein said administering comprises administering the peptide after ischemia, hypoxia, or reperfusion.

64. (New) The method of claim 60, wherein said administering comprises administering the peptide during ischemia, hypoxia, or reperfusion.

Examiner's Amendments to the Specification:

At page 1, line 6, please replace "pending" with — abandoned —.

The following is an **Examiner's Statement of Reasons for Allowance**: The prior art of record does not teach or suggest peptides sharing at least 50% identity to SEQ ID NO: 2 attached to a

Art Unit: 1653

Tat-derived peptide or a polyarginine derived peptide, wherein the peptide inhibits epsilon protein kinase C (ϵ PKC) function in cardiac myocytes. The closest art is a post-filing reference of Chen et al. (October 1, 2001; Chemistry & Biology 8:1123-1129) which teaches the claimed invention. Other prior art is that of Dorn et al. (1999; PNAS 96(22): 12798-12803) which teaches SEQ ID NO: 2 attached to a carrier peptide *Drosophila* Antennapedia. This reference does not teach or suggest to attach SEQ ID NO: 2 to a Tat-derived or polyarginine carrier peptide. Other patents of interest are inventor Mochly-Rosen patents 6,165,977 and 6,855,693. In '977, SEQ ID NO: 6 is the same as instant SEQ ID NO: 2 but this patent does not teach or suggest fusion of SEQ ID NO: 6 to Tat-derived or polyarginine carrier peptides. USP '693 teaches to use Tat-derived and polyarginine carrier peptides with RACK peptides, but does not teach SEQ ID NO: 2. Therefore, the claims are allowable over the art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1653

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink that reads "Karen Cochrane Carlson Ph.D." The signature is written in a cursive, flowing style.

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER